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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,761	04/02/2002	Gregor John McLennan Anderson	PG4029USw	2889
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GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER GLASS, RUSSELL S	
			ART UNIT	PAPER NUMBER
			3626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/089,761	<b>Applicant(s)</b> ANDERSON ET AL.	
	<b>Examiner</b> Russell S. Glass	<b>Art Unit</b> 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12/15/2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in: (1) an application for patent; published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. **Claims 1-7, 9-15, 17, 18, 20-34, 47-56 are rejected under 35 U.S.C. 102(e) as being anticipated by DeLaHeurga, (U.S. 6,408,330).**
2. As per claims 1-3, 9-13, 21, 22, 24, 26, 32 and 54 these claims contain the same or substantially similar limitations as the claims rejected below by reference to DeLaHeurga.
3. As per claim 47, DeLaHeurga discloses a method comprising locally collecting data relevant to the patient's medical condition in electronic form;  
wirelessly communicating with an endpoint to a remote network computer system to enable transfer of said data to said remote network computer system,  
(DeLaHueraga, col. 17, lines 55-60).

permitting authorized user access to the data on the remote network computer system via a secure access gateway, (DeLaHueraga, col. 14, lines 15-27).

4. As per claim 48, DeLaHueraga discloses a method comprising collecting the data on a regular basis, (DeLaHueraga, col. 9, lines 15-23, 55-64).

5. As per claim 49, DeLaHueraga discloses a method comprising collecting the data on a continuous basis, (DeLaHueraga, col. 9, lines 15-23, 55-64).

6. As per claim 50, DeLaHueraga discloses a method comprising wirelessly communicating the data in encrypted form, (DeLaHueraga, col. 15, lines 26-35).

7. As per claim 51, DeLaHueraga discloses a method wherein the data is continuously communicable, (DeLaHueraga, col. 9, lines 15-23, 55-64).

8. As per claim 52, DeLaHueraga discloses a method wherein the data is communicable in packet form, (DeLaHueraga, col. 10, lines 6-12).

9. As per claim 53, DeLaHueraga discloses a method comprising permitting different levels of access to the data to different authorized users, (DeLaHueraga, col. 32, lines 59-66).

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10. As per claim 55, DeLaHeurga discloses a method for remotely assessing a patient's condition and remotely prescribing therefor additionally comprising:

a first authorized user communicating a prescription authorization command to a pharmacy network computer system, (DeLaHeurga, col. 46, line 65-col. 47, line 25);

a second authorized user receiving said prescription authorization command from the pharmacy network computer system, (DeLaHeurga, col. 46, line 65-col. 47, line 25); and

said second authorized user preparing the prescription for the patient based on the prescription authorization, (DeLaHeurga, col. 46, line 65-col. 47, line 25),

wherein the pharmacy network computer system is arranged for communication with the network computer system, (DeLaHeurga, col. 46, line 65-col. 47, line 25).

11. As per claim 56, DeLaHeurga discloses a method wherein the first authorized user communicates the prescription authorization in response to a 'update prescription' alerting signal visible at the patient-specific network address, (DeLaHeurga, col. 4, line 52-col. 5, line 4).

12. As per claim 4, DeLaHeurga discloses a system wherein said patient monitoring system forms part of a compliance monitoring system arranged to monitor patient compliance with a particular treatment regime, (DeLaHeurga, col. 1, lines 35-47).

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13. As per claim 5, DeLaHeurga discloses a system wherein the patient electronic data collection system forms part of a medicament delivery system, and is arranged to collect data when the patient uses the medicament delivery system, (DeLaHeurga, col. 17, lines 36-55).

14. As per claim 6, DeLaHeurga discloses a system wherein the medicament delivery system provides respirable delivery of medicament to the patient, (DeLaHeurga, col. 17, lines 36-55).

15. As per claim 7, DeLaHeurga discloses a system wherein the medicament delivery system provides injectable delivery of medicament to the patient, (DeLaHeurga, col. 17, lines 36-55).

16. As per claim 14, DeLaHeurga discloses a system wherein the authorized users are selected from the group consisting of the patient, a healthcare professional, a pharmacist, an emergency assistance provider, a research professional, a database manager and any combinations thereof, (DeLaHeurga, col. 32, lines 59-66).

17. As per claim 15, DeLaHeurga discloses a system wherein information from a patient-remote datasource is made available to the network computer system, (DeLaHeurga, col. 33, lines 1-5).

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18. As per claim 17, DeLaHeurga discloses a system wherein the patient-remote datasource comprises a database of prescribable medicaments, (DeLaHeurga, col. 46, line 65-col. 47, line 25).

19. As per claim 18, DeLaHeurga discloses a system wherein the patient electronic data collection system further comprises a patient electronic data management system comprising a memory for storage of data, (DeLaHeurga, col. 17, line 66-col. 18, line 1);

a microprocessor for performing operations on said data, (DeLaHeurga, col. 18, lines 10-20); and

a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data, (DeLaHeurga, col. 2, lines 48-55).

20. As per claim 20, DeLaHeurga discloses a system wherein the communicator enables two-way transfer of data between the network computer system and the patient electronic data management system, (DeLaHeurga, col. 18, lines 15,16).

21. As per claim 23, DeLaHeurga discloses a system wherein any communicator employs radiofrequency or optical signals, (DeLaHeurga, col. 39, lines 47-51).

22. As per claim 25, DeLaHeurga discloses a system wherein any communicator includes an embedded network server, (DeLaHeurga, col. 17, line 66-col. 18, line 1).

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23. As per claim 27, DeLaHeurga discloses a system wherein the telecommunications device comprises a cellular phone or pager, (DeLaHeurga, col. 54, lines 39-41).

24. As per claim 28, DeLaHeurga discloses a system wherein the communicator communicates with the second communications device using spread spectrum radiofrequency signals, (DeLaHeurga, col. 18, lines 45-59).

25. As per claim 29, DeLaHeurga discloses a system wherein the network computer system comprises a public access network computer system, (DeLaHeurga, col. 17, lines 55-65).

26. As per claim 30, DeLaHeurga discloses a system wherein the network computer system comprises a private access network computer system, (DeLaHeurga, col. 17, lines 55-65).

27. As per claim 31, DeLaHeurga discloses a system wherein the patient-specific network address is selected from the group consisting of a web-site address, an e-mail address and a file transfer protocol address, (DeLaHeurga, col. 18, lines 37-44).

28. As per claim 33, DeLaHeurga discloses a system wherein said data input system comprises a man machine interface selected from a keypad, graphical user interface



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(GUI), voice recognition interface or biometrics interface, (DeLaHeurga, col. 31, lines 24-26).

29. As per claim 34, DeLaHeurga discloses a system additionally comprising a display for display of data from the patient electronic data management system to the patient, (DeLaHeurga, col. 17, lines 36-54).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. **Claims 35-46 are rejected under 35 U.S.C. 103(a) as being anticipated by DeLaHeurga, (U.S. 6,408,330), in view of Official Notice.**

31. As per claim 35, DeLaHeurga fails to disclose a system for the remote assessment of a patient's respiratory condition additionally comprising a sensor, which senses the breath of a user, wherein the sensor communicates breath data to the patient electronic data collection system. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices

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and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54).

32. As per claim 36, DeLaHeurga fails to disclose a system wherein said sensor comprises a breath-movable element which is movable in response to the breath of a patient. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54).

33. As per claim 37, DeLaHeurga fails to disclose a system wherein said breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54)..

34. As per claim 38, DeLaHeurga fails to disclose a system wherein the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54).

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35. As per claim 39, DeLaHeurga fails to disclose a system wherein the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54).

36. As per claim 40, DeLaHeurga fails to disclose a system wherein the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54).

37. As per claim 41, DeLaHeurga fails to disclose a system wherein the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54).

38. As per claim 42, DeLaHeurga fails to disclose a system wherein the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user. However, such a feature is well-known in the art of ventilators, IV

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pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54).

39. As per claim 43, DeLaHeurga fails to disclose a system wherein said breath data includes breath cycle data. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54).

40. As per claim 44, DeLaHeurga fails to disclose a system wherein said breath data includes peak flow data. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54).

41. As per claim 45, DeLaHeurga fails to disclose a system for the remote assessment of a patient's cardiovascular condition additionally comprising a sensor which senses the cardiovascular activity of a patient, wherein the sensor communicates cardiovascular data to the electronic data collection system. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54).

42. As per claim 46, DeLaHeurga fails to disclose a system wherein said sensor measures the blood pressure of the patient. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54)..

**43. Claims 8, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLaHeurga, (U.S. 6,408,330), in view of Thompson, (U.S. 6,083,248).**

44. As per claim 8, DeLaHeurga fails to disclose a system, wherein the medicament delivery system is an implant in the body of the patient. However, such a feature is well-known in the art as evidenced by Thompson, (Thompson, Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine DeLaHeurga and Thompson. The motivation would have been to enhance the ability of the medical system to find patients and get reports on patient and medical device status, and update medical device programming, (Thompson, Abstract).

45. As per claim 16, DeLaHeurga fails to disclose a system wherein the patient-remote datasource comprises data relating to ambient environmental conditions.

However, such a feature is well-known in the art as evidenced by Thompson, (Thompson, Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine DeLaHeurga and Thompson. The motivation would have been to enhance the ability of the medical system to find patients and get reports on patient and medical device status, and update medical device programming, (Thompson, Abstract).

46. As per claim 19, DeLaHeurga fails to disclose a system wherein said patient electronic data management system additionally comprises a geographic positioning system. However, such a feature is well-known in the art as evidenced by Thompson, (Thompson, Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine DeLaHeurga and Thompson. The motivation would have been to enhance the ability of the medical system to find patients and get reports on patient and medical device status, and update medical device programming, (Thompson, Abstract).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell S. Glass whose telephone number is 571-272-3132. The examiner can normally be reached on M-F 8-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RSG  
3/1/2007

RS6

Carolyn Bleck  
Patent Examiner - 3626  
3/2/07